

**Notice of Allowability**

Application No.

10/784,916

Examiner

Anthony J. Paviglianiti

Applicant(s)

VAZQUEZ ET AL.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment to claims dated June 15, 2005.
2. ☒ The allowed claim(s) is/are 1,66,78,126,132 and 167.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All    b) ☐ Some\*    c) ☐ None    of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_



### **DETAILED ACTION**

Applicant's "Amendment to the Claims" and "Remarks" dated June 15, 2005, have been entered. **Claims 1, 66, 78, 126, 132 and 167** are currently pending in the application. **Claims 68 – 72, 127 – 131, 168 – 169 and 172** were cancelled by Examiner's Amendment with authorization from Applicant, below.

### **Priority**

This application is a Continuation application of U.S. Patent Application No. 10/237,184 filed September 9, 2002 (now U.S. Patent No. 6,727,282), which is a Continuation application of U.S. Patent Application No. 09/884,462 filed June 20, 2001 (now U.S. Patent No. 6,469,207), which is a Continuation application of U.S. Patent Application No. 09/419,816 filed October 18, 1999 (now U.S. Patent No. 6,313,345), which is a Continuation application of U.S. Patent Application No. 09/041,016 filed March 12, 1998 (now U.S. Patent No. 6,022,994), which is a Continuation application of U.S. Patent Application No. 08/541,747 filed October 10, 1995 (now U.S. Patent No. 5,760,076), which is a Divisional application of U.S. Patent Application No. 08/110,912 filed August 24, 1993 (now U.S. Patent No. 5,463,104), which is a Continuation-in-Part application of U.S. Patent Application No. 07/935,490 filed August 25, 1992, which was abandoned.

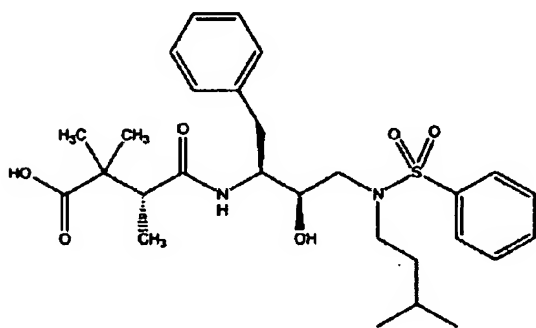
### **Information Disclosure Statement**

The Information Disclosure Statements filed on February 24, 2004, August 18, 2004, and August 25, 2004, are in compliance with 37 C.F.R. §1.97 and were considered by the examiner in the first Office Action (dated March 15, 2005).

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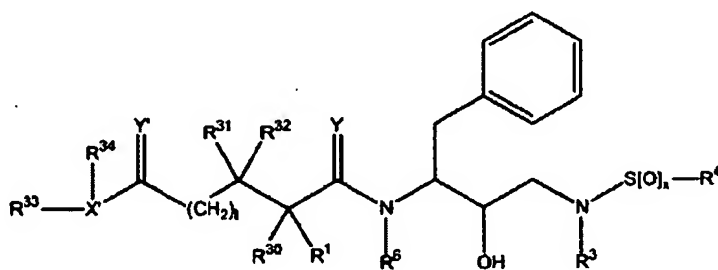
**Election/Restrictions**

Applicant's written affirmation of the provisional election by telephone of the invention of **Group I** in the Response to Restriction Requirement (dated June 15, 2005) is hereby acknowledged. Applicant's written affirmation of the provisional election by telephone of the compound [1S-[1R\*(S\*),2S\*]]-4-[[2-hydroxy-3-[(3-methylbutyl) (phenyl-sulfonyl)amino]-1-(phenylmethyl)propyl]amino]-2,2,3-trimethyl-4-oxo-butanoic acid, with chemical structure:



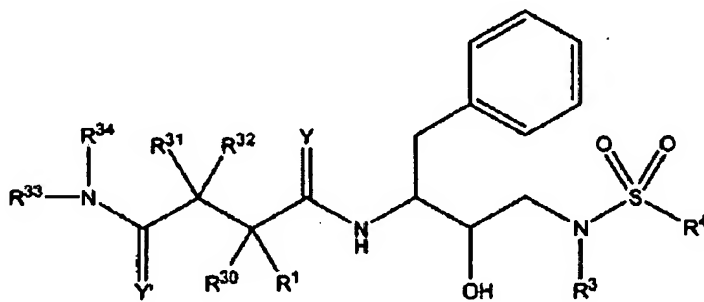
, is also acknowledged.

The elected invention, **Group I**, was defined in the restriction requirement in the first Office Action as **Claims 1, 66, 78, 126, 132, and 167**, drawn to chemical compounds and



compositions having structures of:

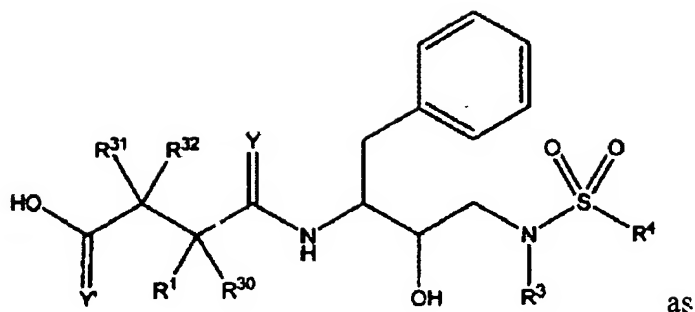
, as



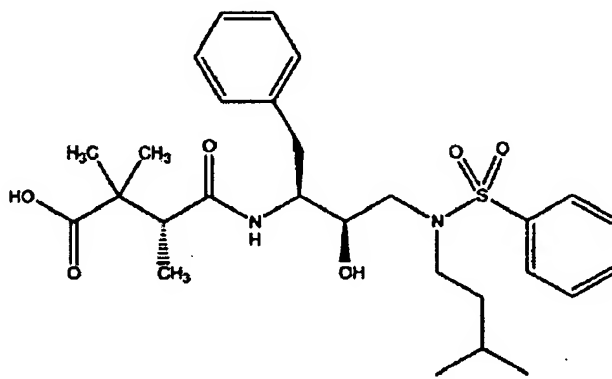
depicted in **Claim 1** (as amended);

, as

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depicted in **Claim 78** (as amended); anddepicted in **Claim 132** (as amended).

Applicant's election of Group I and of the compound had been made "with traverse"; the examiner's "response to traverse" was made in the first Office Action (March 15, 2005; page 9, line 12 to page 11, line 2). Applicant has requested full examination on the merits of elected **Claims 1, 66, 78, 126, 132 and 167**, citing MPEP §803.02. However, in the first



Office Action, the elected compound,

, was

found in the prior art and rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **U.S. Patent No. 5,463,104**, "Claim 14" (3<sup>rd</sup> compound), at col. 59, lines 2 – 5, in which the elected compound, [1S-[1R\*(S\*),2S\*]]-4-[[2-hydroxy-3-[(3-methylbutyl) (phenyl-sulfonyl)amino]-1-(phenylmethyl)propyl]amino]-2,2,3-trimethyl-4-oxo-butanoic acid, had already been patented by these same inventors and assignee, and was the basis for the double patenting rejection in the first Office Action. As will be described below, this rejection has been overcome by applicant's Terminal Disclaimer, and the

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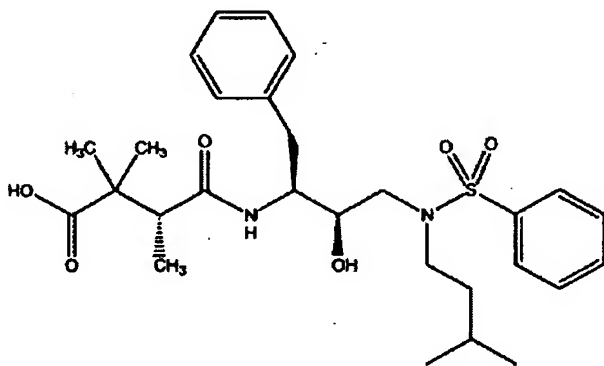
search of the art for the invention was expanded to encompass the full extent of the genus compounds and compositions in Claims 1 and 66, Claims 78 and 126, and Claims 132 and 167, respectively, consistent with the applicant's argument.

Applicant's cancellation of Claims 68 – 72, 127 – 131, 168 – 170 and 172 (see below) moots the arguments regarding these claims.

### Prior Art Searched

#### 1) *the elected compound*

The elected compound (see section above) was searched in the art, but was found to be previously patented by the same inventive entity and assignee. This was the basis for the Obviousness-type Double Patenting rejection in the first Office Action in this matter on March 15, 2005. Specifically, the elected compound, [1S-[1R\*(S\*),2S\*]]-4-[[2-hydroxy-3-[(3-methylbutyl) (phenyl-sulfonyl)amino]-1-(phenylmethyl)propyl]amino]-2,2,3-trimethyl-4-oxo-



butanoic acid,

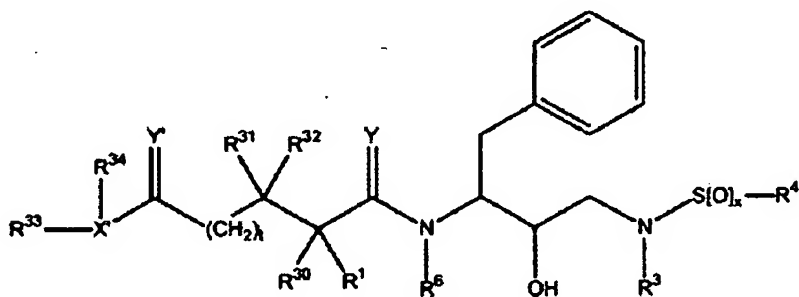
, was patented in U.S. Patent No.

5,463,104, as the third compound in Claim 14, at col. 59, lines 2 – 5. However, this rejection was overcome by a Terminal Disclaimer by Applicant, and the search of the art was expanded, as described below.

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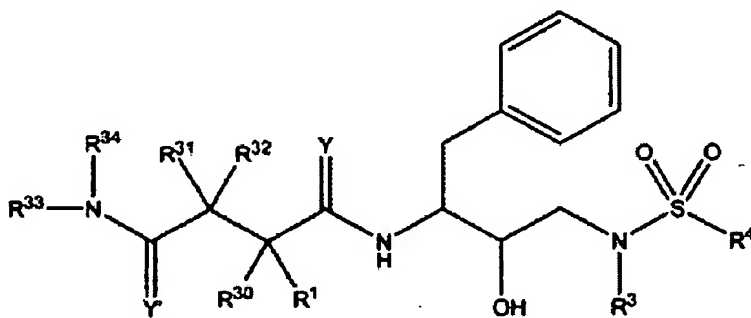
## 2) *Expansion of search beyond the elected compound*

The search of the art was expanded in a series of searches to include compounds and compositions in the same (and related) classifications as the elected compound. No competent art of a sufficient date to anticipate or render obvious the compounds was found. Therefore, the search was expanded again to encompass the full scope of compounds and compositions within

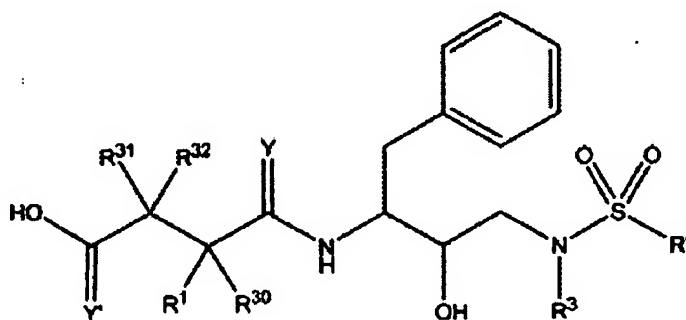


the genus structures:

, as depicted

in **Claim 1** (as amended), and

, as

depicted in **Claim 78** (as amended), and

as depicted in **Claim 132** (as amended). No prior art was found which anticipated or rendered obvious these compounds and compositions. The closest prior art is described below.

**Terminal Disclaimer**

Applicant's Terminal Disclaimer, filed June 15, 2005, is hereby acknowledged, and was approved by the USPTO, effective June 15, 2005.

**Response to Amendments**

The first Office Action, dated March 15, 2005, rejected **Claims 1 and 66, Claims 78 and 126, and Claims 132 and 167** because of Obviousness-type Double Patenting over **U.S. Patent No. 5,463,104**. These rejections were each overcome by Applicant's Terminal Disclaimer filed June 15, 2005. No new matter was added.

**Examiner's Amendment**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Agreement for the following examiner's amendment was reached in a telephone interview with Joseph M. Skerpon, Esq., on August 11, 2005, who authorized the following amendments:

In **Claim 1**, page 2, line 4, delete “, prodrug, or ester” after the word salt.

Delete **Claim 68**.

Delete **Claim 69**.

Delete **Claim 70**.

Delete **Claim 71**.

Delete **Claim 72**.

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In **Claim 78**, page 4, line 7, delete “, prodrug, or ester” after the word salt.

Delete **Claim 127**.

Delete **Claim 128**.

Delete **Claim 129**.

Delete **Claim 130**.

Delete **Claim 131**.

In **Claim 132**, page 6, line 3, delete “, prodrug, or ester” after the word salt.

Delete **Claim 168**.

Delete **Claim 169**.

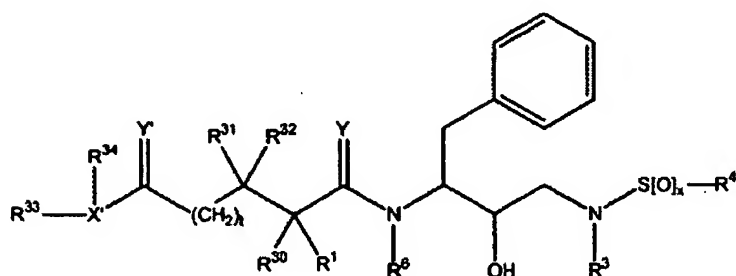
Delete **Claim 170**.

Delete **Claim 172**.

A summary of this telephone interview may also be found on Form PTOL-413, dated August 11, 2005. The deleted claims were cancelled by applicant without prejudice to pursue in a future continuing or divisional application. It is not necessary for applicant to provide a separate record of the substance of the telephone interview of August 11, 2005.

### **Reasons for Allowance**

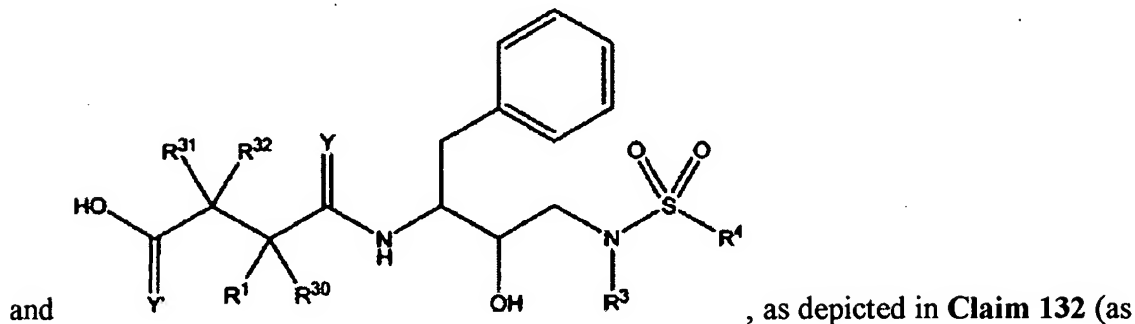
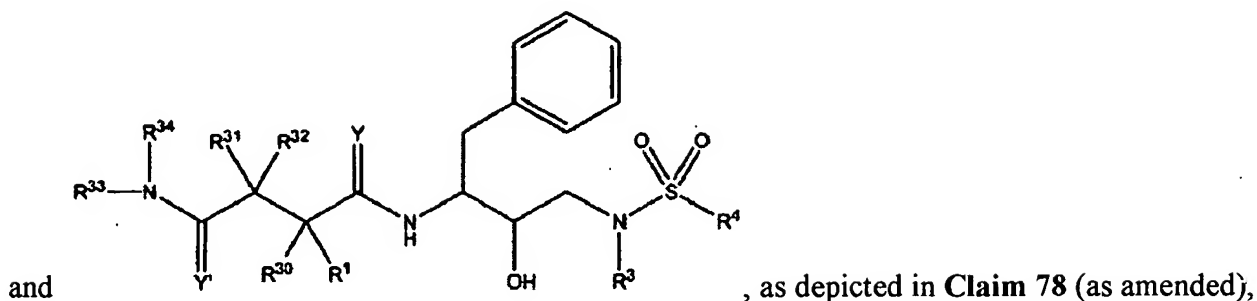
The following is an examiner's statement of the reasons for allowance: The present invention is directed to chemical compounds and compositions having the structure



, as depicted in **Claim 1** (as amended),



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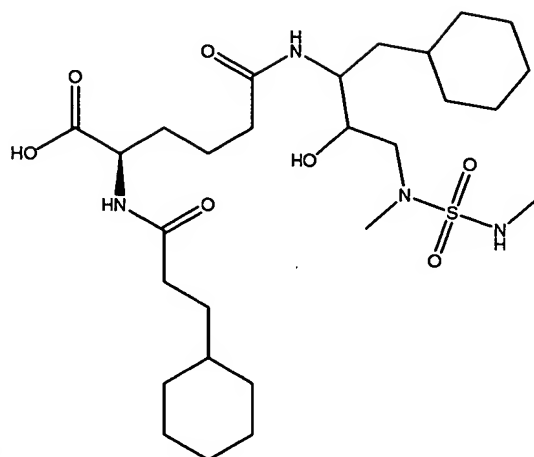


amended), wherein variables  $x$ ,  $t$ ,  $R^1$ ,  $R^3$ ,  $R^4$ ,  $X'$ ,  $Y$ ,  $Y'$ ,  $R^6$ ,  $R^{15}$ ,  $R^{30}$ ,  $R^{31}$ ,  $R^{32}$ ,  $R^{33}$ , and  $R^{34}$  are as defined in **Claims 1, 78 and 132** (as amended), which are disclosed as having utility as inhibitors of retroviral protease.

As described above, the search of the art encompassed the entire scope of the compounds and compositions as defined in the claims, which were found to be free of the prior art. Applicant's Terminal Disclaimer obviated all of the Double Patenting rejections brought in the first Office Action.

The closest prior art to the present invention was disclosed in **GB 2 200 115 A** (Hagenbach, et al.), published July 27, 1988, which disclosed the compound "(2S,3S)-3-(3-cyclohexyl-propionyl-norleucyl) amido-4-cyclohexyl-1-dimethylsulphamoylamino-2-butanol,"

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which has the structure:

(see GB 2 200 115 A, at claim

4, page 75, lines 15 – 16; see also “Example 28” at p. 34). This reference was appropriately included on Applicant’s Information Disclosure Statement and will not be separately listed on the examiner’s references cited on Form 892. While this compound meets many of the limitations of the pending claims, the prior art differs from the compounds and compositions of the present invention because the substituent at the 4-position of the butanol component is a *cyclohexyl* group rather than a *phenyl* group; in addition, the present invention limits the alkyl chain “(CH<sub>2</sub>)<sub>t</sub>” to compounds where *t* is 0 or 1, while the compound in the prior art is equivalent to an alkyl chain where *t* is 2 and has a *cyclohexyl propanamide* substituent that is not within the permitted scope of the limitations of substituent **R**<sup>1</sup>. Thus the compound disclosed in GB 2 200 115 A, which was determined to be the closest prior art, does not meet (or render obvious) all of the limitations for the compounds and compositions in the present invention.

Therefore, for the reasons in the analysis above, **Claims 1, 66, 78, 126, 132 and 167** are neither anticipated nor rendered obvious over the prior art of record, and are allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should accompany the issue fee. Such submissions should be clearly labeled as “Comments on Statement of Reasons for Allowance.”

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**Conclusion**

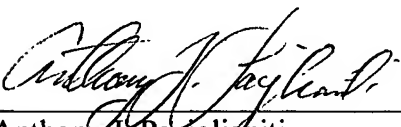
**Claims 1, 66, 78, 126, 132 and 167** (as amended) are allowed.


**Claims 68 – 72, 127 – 131, 168 – 170 and 172** were cancelled by examiner's amendment authorized by applicant.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Anthony J. Paviglianiti** whose telephone number is **(571) 272-3107**. The examiner can normally be reached on Monday-Friday, 8:30 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached at (571) 272-0699. **The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Please note that this is a new central FAX number for all official correspondence.**

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
Anthony J. Paviglianiti  
Patent Examiner  
TC-1600, Art Unit 1626

  
\_\_\_\_\_  
**TAOFIQ SOLOLA**  
**PRIMARY EXAMINER**

  
\_\_\_\_\_  
Joseph K. McKane  
Supervisory Patent Examiner  
TC-1600, Art Unit 1626